How Hospitals Can Meet Premarket Requirements

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Outline

- Premarket Requirements Basics Discussed This Morning
- The Challenges for the Hospital as a Manufacturer
- Data Requirements Summary
- Engineering/Preclinical/Clinical Data
- Sources for guidance and assistance

Recap

- Premarket notifications for Class II devices; based on comparisons to marketed devices showing new device is as safe and effective
- Premarket approval for Class III devices; based on valid scientific evidence showing device is safe and effective
- Generally easier to get to market with a 510(k)

The Challenge to Hospitals

New responsibilities

- **premarket submissions**
- quality systems
- postmarket reporting
- audits
- registration and other reports
- oversight of contractors

Challenge

- Premarket responsibilities
  - design control activities
    - verifications
    - validations
  - changes to OEM device
  - labeling
  - packaging

Challenge

- Understand the requirements and scope of the tasks
- Assess capabilities and resources
- Seek expertise and counsel including interaction with FDA
- Decide what will be done and by whom
- Execute plan!

Data Requirements

510(k)

- Descriptive Data (Primary Decision Level)
  - labeling comparisons
  - specification comparisons
  - some process information
- Performance Data (If Needed)
  - specific tests to show equivalent performance
  - can be simple to complex

Data Requirements

- PMA
  - descriptive data
  - labeling
  - engineering tests
  - preclinical
  - clinical data
  - manufacturing information

Engineering/Preclinical/Clinical Data

How do I know what tests are needed?

- As determined by design control process
- As noted in FDA guidance
- As needed according to standard that is utilized
- As completed by OEM or predicate device
- As determined by risk analysis
- As needed based on change to device

Sources for Guidance and Assistance

- Division of Small Maufacturers Assistance
- FDA and CDRH web address
- Meeting or discussion with Office of Device Evaluation and other CDRH offices as needed
- Information through FOI
- Outside sources